

NOV 10 2004

Chapter 1 – Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K04 2475

- 1. Submitter name, address, contact** Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4041
Contact Person: Marlene A. Hanna
Email: mhanna1@ocdus.jnj.com

- 2. Preparation Date** Date 510(k) prepared: September 10, 2004
- 3. Device name(s)** **Trade or Proprietary Name(s):**
VITROS Chemistry Products IgG Reagent
VITROS Chemistry Products IgA Reagent
VITROS Chemistry Products IgM Reagent
VITROS Chemistry Products Calibrator Kit 20
VITROS Chemistry Products Protein Performance Verifiers I, II, and III

Common Name(s):
Immunoglobulin G (IgG) assay
Immunoglobulin A (IgA) assay
Immunoglobulin M (IgM) assay

Classification Name(s):
Immunoglobulins A, G, M, D, and E immunological test system (866.5510): Class: II (performance standards).

Calibrator (862.1150): Calibrator Kit 20: Class II.

Quality Control material (assayed and unassayed) (862.1660): Class I (general controls). Since these devices (Protein Performance Verifiers I, II, and III) are assayed controls, they meet the reserved criteria under Section 510(I) of the Food, Drug, and Cosmetic Act.

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510(k) Summary, Continued

4. Predicate Devices

- a. The VITROS Chemistry Products IgG, IgA, and IgM Reagents and Calibrator Kit 20 are substantially equivalent to the Dade Behring N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) and Dade Behring N Protein Standard SL (human).
- b. The VITROS Chemistry Products Protein Performance Verifiers I, II, and III are substantially equivalent to the Dade Behring N/T Protein Controls S/L.

5. Device description

The VITROS 5,1 FS Chemistry System is a fully automated clinical chemistry analyzer intended for use in the *in vitro* determination of various analytes in human specimens (serum, plasma, urine, and cerebrospinal fluid). The VITROS 5,1 FS is designed for use with VITROS Chemistry Products MicroTip and Thin Film assays.

The system is comprised of four main elements:

1. The VITROS 5,1 FS Chemistry System – instrumentation, which provides automated use of the chemistry reagents. The VITROS 5,1 FS Chemistry System was cleared for market by a separate 510(k) premarket notification (K031924).
2. The VITROS Chemistry Products MicroTip range of liquid reagent products (in this case VITROS Chemistry Products IgG, IgA, and IgM Reagents and VITROS Chemistry Products Calibrator Kit 20, and VITROS Chemistry Products Protein Performance Verifiers I, II, and III), which are combined by the VITROS 5,1 FS Chemistry System to perform the VITROS IgG, IgA, and IgM assays.
3. The VITROS Chemistry Products Thin Film range of dry products, which are dry, multilayered, analytical elements, coated on polyester supports. The thin film products each have their own 510(k) clearance numbers and were cleared for market for use on the VITROS 5,1 FS Chemistry System through submission of information required by the ODE Guidance Document: “Data For Commercialization Of Original Equipment Manufacturer, Secondary and Generic Reagents For Automated Analyzers”. The required information was provided in the VITROS 5,1 FS Chemistry System premarket notification (K031924).
4. Common reagents used by multiple assays on the VITROS System (in this case, VITROS Chemistry Products FS Diluent Pack 2 (BSA/ Saline).

The VITROS System and reagents are designed specifically for use with the VITROS Chemistry Products range of products.

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**6. Device(s)
intended
use**

VITROS Chemistry Products IgG Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products IgG Reagent is used to quantitatively measure immunoglobulin G (IgG) concentration in human serum and plasma.

VITROS Chemistry Products IgA Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products IgA Reagent is used to quantitatively measure immunoglobulin A (IgA) concentration in human serum and plasma.

VITROS Chemistry Products IgM Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products IgM Reagent is used to quantitatively measure immunoglobulin M (IgM) concentration in human serum and plasma.

VITROS Chemistry Products Calibrator Kit 20: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 20 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of transferrin, C3, C4, IgG, IgA and IgM.

VITROS Chemistry Products Protein Performance Verifiers I, II, and III: For *in vitro* diagnostic use only. VITROS Chemistry Products Protein Performance Verifiers I, II, and III are assayed controls used to monitor the performance of TRFRN, C3, C4, IgG, IgA and IgM Reagents on VITROS 5,1 FS Chemistry Systems.

**7. Comparison
to predicate
device(s):**

IgG, IgA, and IgM Reagents and Calibrator Kit 20

The VITROS Chemistry Products IgG, IgA, and IgM Reagents and VITROS Chemistry Products Calibrator Kit 20 are substantially equivalent to K860894, the Dade Behring N Antisera to Human Immunoglobulins (IgG, IgA, and IgM), and K012470, Dade Behring N Protein Standard SL (predicate devices) which were cleared by the FDA for IVD use.

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IgG Reagent and Calibrators

The relationship between the VITROS IgG and the predicate device, determined by least squares linear regression, is:

$$\text{VITROS IgG} = 0.98x + 91.2 \text{ (mg/dL)},$$

with a correlation coefficient of 0.995,
where X is the Dade Behring N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) assay.

IgA Reagent and Calibrators

The relationship between the VITROS IgA and the predicate device, determined by least squares linear regression, is:

$$\text{VITROS IgA} = 1.07x - 3.03 \text{ (mg/dL)},$$

with a correlation coefficient of 0.999,
where X is the Dade Behring N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) assay.

IgM Reagent and Calibrators

The relationship between the VITROS IgM and the predicate device, determined by least squares linear regression, is:

$$\text{VITROS IgM} = 1.02x + 1.1 \text{ (mg/dL)},$$

with a correlation coefficient of 0.998,
where X is the Dade Behring N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) assay.

In addition to the above mentioned correlation study, studies were performed to determine the precision, specificity, linearity, antigen excess, lower limit of detection, and expected values of the VITROS IgG, IgA and IgM assays, (refer to the VITROS IgG, IgA, and IgM Reagent's Instructions for Use for summaries of the results of these studies).

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Table 1 lists the characteristics of the assays performed using the VITROS IgG, IgA, and IgM assays and the Dade Behring N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) assay.

Table 1 Table 1 lists the characteristics of the VITROS IgG, IgA, and IgM Reagent (new devices) and the DADE IgG, IgA, and IgM assays (predicate device).

Device Characteristic	VITROS IgG, IgA and IgM (New device)	DADE IgG, IgA, and IgM (Predicate device)
Intended Use	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products IgG , IgA, and IgM Reagents are used to quantitatively measure immunoglobulin G (IgG), immunoglobulin A (IgA), and immunoglobulin M(IgM) concentration in human serum.	<i>In vitro</i> diagnostic reagents for the quantitative determination of immunoglobulins (IgG, IgA, and IgM) in human serum as well as of IgG in human CSF.
Method	Immunturbidimetric	Immunturbidimetric
Reportable Range:		
IgG:	270 – 2700 mg/dL	140 - 4600 mg/dL
IgA:	40 – 800 mg/dL	25 – 800 mg/dL
IgM:	25 – 400 mg/dL	20 – 640 mg/dL
Sample Type	Human Serum	Human Serum
Reactive Ingredients		
IgG:	Goat antisera to human IgG	Rabbit antisera to human IgG
IgA:	Goat antisera to human IgA	Rabbit antisera to human IgA
IgM:	Goat antisera to human IgM	Rabbit antisera to human IgM
Instrumentation	VITROS 5,1 FS Chemistry System	DADE BN ProSpec

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Performance Verifiers

The VITROS Chemistry Products Protein Performance Verifiers I, II, and III are substantially equivalent to the Dade Behring N/T Protein Controls SL (predicate device) which was cleared by the FDA (K012468) for IVD use.

Table 2 lists the similarities and differences of the device characteristics between the VITROS Protein Performance Verifiers I, II, and III with the predicate device, the Dade Behring N/T Protein Controls SL.

Table 2

Device Characteristic	VITROS Protein Performance Verifiers (New Device)	DADE Protein Controls (Predicate Device)
Intended Use	For <i>in vitro</i> diagnostic use only. VITROS Chemistry Products Protein Performance Verifiers I, II, and III are <u>assayed controls</u> used to monitor the performance of TRFRN, C3, C4, IgG, IgA and IgM Reagents on VITROS 5,1 FS Chemistry Systems.	For <i>in vitro</i> diagnostic use only. N/T Protein Controls S/L is for use as accuracy and precision <u>assayed controls</u> in the determination of the following human serum proteins by immunonephelometry with BN™ Systems: IgG _{1,4} , IgA, IgM, C3c, C4, Transferrin, Albumin, α ₁ -antitrypsin, α ₂ macroglobulin, Haptoglobin, α ₁ -acid glycoprotein, Prealbumin, Hemopexin, Ceruloplasmin, RbP, Ig/L-chain lambda & Kappa, β ₂ -microglobulin, soluble Transferrin Receptor (sTfR), Ferritin, IgE, Total protein.
Matrix	Processed human serum to which inorganic salts, buffers, and preservatives have been added.	Human serum with stabilizers and preservatives.
Form	Liquid	Liquid
Volume	1 mL per vial	1 mL per vial

Conclusions The data presented in the premarket notification provide a reasonable assurance that the VITROS IgG, IgA, and IgM reagents, Calibrator Kit 20, and the VITROS Chemistry Products Protein Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices.

Equivalence to predicate(s) was demonstrated using commercially available reagents along with patient samples.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 10 2004

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Marlene A. Hanna
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626

Re: k042475
Trade/Device Name: VITROS Chemistry Products IgG Reagent
VITROS Chemistry Products IgM Reagent
VITROS Chemistry Products IgA Reagent
VITROS Chemistry Products Calibrator Kit 20
VITROS Chemistry Products Protein Performance Verifiers I, II,
and III
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, E immunological test system
Regulatory Class: Class II
Product Code: CFN, JIX, JJY
Dated: September 10, 2004
Received: September 13, 2004

Dear Ms. Hanna:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed

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predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific information about the application of labeling requirements to your devices, or questions on the promotion and advertising of your devices, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert L. Becker, Jr." with a stylized flourish at the end.

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use for the IgA assay

510(k) Number (if known):

K042475

Device Name(s):

VITROS Chemistry Products IgA Reagent
VITROS Chemistry Products Calibrator Kit 20
VITROS Chemistry Products Protein Performance Verifiers I, II, and III

Indications for Use:

For *in vitro* diagnostic use only. VITROS Chemistry Products IgA Reagent is used to quantitatively measure immunoglobulin A (IgA) concentration in human serum and plasma.

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 20 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of transferrin, C3, C4, IgG, IgA and IgM.

For *in vitro* diagnostic use only. VITROS Chemistry Products Protein Performance Verifiers I, II, and III are assayed controls used to monitor the performance of TRFRN, C3, C4, IgG, IgA and IgM Reagents on VITROS 5,1 FS Chemistry Systems.

Prescription Use ✓
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Per 21 CFR 807 Subpart C)

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Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042475

Indications for Use for the IgM assay

510(k) Number (if known): K042475

Device Name(s): VITROS Chemistry Products IgM Reagent
VITROS Chemistry Products Calibrator Kit 20
VITROS Chemistry Products Protein Performance Verifiers I, II, and III

Indications for Use: For *in vitro* diagnostic use only. VITROS Chemistry Products IgM Reagent is used to quantitatively measure immunoglobulin M (IgM) concentration in human serum and plasma.

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 20 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of transferrin, C3, C4, IgG, IgA and IgM.

For *in vitro* diagnostic use only. VITROS Chemistry Products Protein Performance Verifiers I, II, and III are assayed controls used to monitor the performance of TRFRN, C3, C4, IgG, IgA and IgM Reagents on VITROS 5,1 FS Chemistry Systems.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

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